

Attorney Docket No. 38163-0010

Serial No. 08/455,975

**REMARKS**

Claims 38-45, 57-62, 64-86, 88-89, 91-109, 111-119, 132-133, 136-137, 140-147, 149 and 150-193 are pending in this application. Claims 152, 175 and 176 are herewith canceled and no new claims are added. Thus, with entry of the above amendment, claims 38-45, 57-62, 64-86, 88-89, 91-109, 111-119, 132-133, 136-137, 140-147, 149-151, 153-174, and 177-193 will be active in this case. A marked-up copy of the claims showing the amendment is attached.

**I. ALLOWABILITY**

Applicants thank Examiner Saoud for indicating that claims 38-45, 57-62, 64-86, 88, 89, 91-109, 111-119, 132, 133, 136, 137, 140-147 and 149 are allowable. The amendments to claims 45, 62 and 89 harmonize the language with similar pending claims and add no new matter. Entry of the amendments and maintenance of allowance is respectfully requested.

**II. CLAIM OBJECTIONS**

The Examiner has objected to claim 152 and claim 178 for being in improper dependent form for not further limiting the base claim. Because applicants have herewith canceled claim 152 and have amended claim 178 to harmonize with the language suggested by the Examiner in connection with claim 154, this objection is moot. Applicants also amend claim 154, pursuant to the Examiner's suggestion. No new matter is added with the amendment.

The Examiner further asserts that claims 175 and 176 are substantial duplicates of claims 73 and 76. Given that applicants have canceled claims 175 and 176, this objection is now moot.

**III. REJECTIONS UNDER 35 USC § 112, FIRST PARAGRAPH**

In paragraph 8 of the Official Action, the Examiner rejects claims 155-162, 177-193. Specifically, the Examiner asserts that the "segments" of the polypeptides must be characterized as having mitogenic activity. In response, applicants have amended the rejected claims. No new matter is added with this amendment.

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In paragraphs 9 and 10 of the Official Action, the Examiner rejects claims 150-174 and 177-193 under 35 USC § 112, second paragraph, for the alleged reason that the claims are unclear for reciting "a DNA encoding a polypeptide *having a sequence* comprising amino acids 32-194" and requests applicants to eliminate "having a sequence" from such phrase. In response, applicants have made this change throughout the claims.

Examiner Saoud also indicates that in view of the objection to claim 152, applicant should amend claim 154 such that it depends from claim 150. Applicants have responded by following the Examiner's suggestion.

The Examiner also rejects claims 155, 163, 167, 171, 177, 181 and 190 for reciting "amino acid sequence 32-194" and has suggested alternative language. In response, Applicants have followed the Examiner's advice.

Applicants respectfully assert that each of the Examiner's objections and rejections has been addressed, pursuant to the Examiner's suggestion, or has been rendered moot. Therefore, Applicants request the Examiner to withdraw each of the objections and rejections and move this case to allowance.

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CONCLUSION

Applicants assert that the entry of the above amendment after final is proper in view of the fact that the amendments either render objections moot or directly respond to Examiner Saoud's suggestions and would place this case in condition for allowance. In the event there are still issues that need to be resolved prior to the issuance of such allowance, Applicants undersigned attorney invite Examiner Saoud to contact her at the number below.

Respectfully submitted,

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Date

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## MARKED-UP COPY OF CLAIMS, WITH AMENDMENT

45. (Amended) The method of claim 38, wherein said polypeptide is [administered] formulated in a pharmaceutical composition comprising a pharmaceutically acceptable carrier.

62. (Amended) The method of claim 57, wherein said polypeptide is [administered] formulated in a pharmaceutical composition comprising a pharmaceutically acceptable carrier.

89. (Amended) The method of claim 88, wherein said polypeptide is [administered] formulated in a pharmaceutical composition comprising a pharmaceutically acceptable carrier.

92. (Amended) The method of claim [90] 82, wherein said polypeptide further comprises Met at the N-terminus.

93. (Amended) The method of claim [90] 82, wherein said polypeptide is unglycosylated.

95. (Amended) The method of claim [87] 82, wherein the polypeptide consists of (a) a sufficient number of amino acids 32-64 of Figure 7 that said polypeptide has epithelial cell specificity, and (b) amino acids 65-194 of Figure 7.

150. (Amended) A method of stimulating epithelial cells comprising administering to a patient in need thereof an epithelial cell stimulating amount of a keratinocyte growth factor (KGF) polypeptide prepared by expressing a DNA encoding a polypeptide [having a sequence] comprising amino acids 32 - 194 of Figure 7.

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154. (Amended) The method of claim [152] 150, wherein said [cell is selected from the group consisting of] DNA is expressed in a bacterial cell, a fungal cell, a mammalian cell [and] or an insect cell.

155. (Amended) A method of stimulating epithelial cells comprising administering to a patient in need thereof an epithelial cell stimulating amount of a keratinocyte growth factor (KGF) polypeptide comprising [the] amino acids [sequence] 32 to 194 of Figure 7 or a segment of said [sequence] polypeptide, wherein said polypeptide and said segment of said polypeptide have [has] mitogenic activity on BALB/MK cells.

163. (Amended) A method of stimulating epithelial cells comprising administering to a patient in need thereof an epithelial cell stimulating amount of a keratinocyte growth factor (KGF) polypeptide comprising [the] amino acids [sequence] 32-194 of Figure 7 or a segment of said [sequence] polypeptide, wherein the segment is that part of the amino acid sequence of Figure 7 that remains after the amino acid sequence of Figure 7 is truncated from an N terminus to C terminus direction, within the region of amino acids 32-78.

165. (Amended) The method of claim 163 wherein said polypeptide and said segment of said polypeptide has mitogenic activity on BALB/MK keratinocyte cells.

166. (Amended) The method of claim 163, wherein said polypeptide and said segment of said polypeptide stimulates mitogenic activity [in] on epithelial cells.

167. (Amended) A method of stimulating epithelial cells comprising administering to a patient in need thereof an epithelial cell stimulating amount of a keratinocyte growth factor (KGF) polypeptide comprising a keratinocyte growth factor (KGF) polypeptide comprising amino acids [sequence] 32-194 of Figure 7 or a segment of said [sequence] polypeptide, wherein the segment is that part of the amino acid sequence of Figure 7 that remains after the amino acid sequence of Figure 7 is truncated from the C terminus toward the N terminus, within the region of amino acids 194 to 189.

169. (Amended) The method of claim 167, wherein said polypeptide and said segment of said polypeptide have [has] mitogenic activity on BALB/MK keratinocyte cells.

170. (Amended) The method of claim 167, wherein said polypeptide and said segment of said polypeptide stimulates mitogenic activity in epithelial cells.

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171. (Amended) A method of stimulating epithelial cells comprising administering to a patient in need thereof an epithelial cell stimulating amount of a keratinocyte growth factor (KGF) polypeptide comprising amino acids [sequence] 32-194 of Figure 7 or a segment of said [sequence] polypeptide, wherein the segment is that part of the amino acid sequence of Figure 7 that remains after the amino acid sequence of Figure 7 is truncated from an N terminus to C terminus direction, within the region of amino acids 32-78 and is truncated from the C terminus toward the N terminus, within the region of amino acids 194 to 189.

173. (Amended) The method of claim 171, wherein said polypeptide and said segment of said polypeptide have [has] mitogenic activity on BALB/MK keratinocyte cells.

177. (Amended) A method of stimulating epithelial cells comprising administering to a patient in need thereof an epithelial cell stimulating amount of a keratinocyte growth factor (KGF) polypeptide, wherein said polypeptide is prepared by expressing a DNA encoding a polypeptide comprising [the] amino acids [sequence] 32-194 of Figure 7 or a segment of said [sequence] polypeptide, wherein the segment is that part of the amino acid sequence of Figure 7 that remains after the amino acid sequence of Figure 7 is truncated from an N terminus to C terminus direction, within the region of amino acids 32-78.

178. (Amended) The method of claim 177, wherein the DNA is expressed in [in isolated host] a bacterial cell, a fungal cell, a mammalian cell or an insect cell.

180. (Amended) The method of claim 177, wherein said polypeptide and said segment of said polypeptide has mitogenic activity on BALB/MK keratinocyte cells.

181. (Amended) A method of stimulating epithelial cells comprising administering to a patient in need thereof an epithelial cell stimulating amount of a keratinocyte growth factor (KGF) polypeptide comprising [the] amino acids [sequence] 32 to 194 of Figure 7 or a segment of said [sequence] polypeptide, wherein said polypeptide and said segment of said polypeptide stimulates mitogenic activity in epithelial cells.

190. (Amended) A method of stimulating epithelial cells comprising administering to a patient in need thereof an epithelial cell stimulating amount of a keratinocyte growth factor (KGF) polypeptide comprising a segment of [the] amino acids [sequence] 32-194 of Figure 7, wherein the segment is that part of the amino acid sequence of Figure 7 that remains after the

amino acid sequence of Figure 7 is truncated from an N terminus to C terminus directio 1,  
within the region of amino acids 32-78, and wherein said polypeptide is unglycosylated.

191. (Amended) The method of one of claims 150-151, 153-174, 177-189 [to 18<sup>0</sup>],  
wherein said polypeptide is unglycosylated.

192. (Amended) The method of one of claims 150-151, 153-174, 177-189 [to 18<sup>0</sup>],  
wherein said polypeptide is glycosylated.